DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 14, 2016

Primus Gloves PVT Limited
Jose Paul M
Manager—QA & RA
Plot No: 14-A, Cochin Special Economic Zone
Kakkanad, Cochin, Kerala 682037
INDIA

Re: K143477
Trade/Device Name: Nitrile Patient Examination gloves, Powderfree, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: undated
Received: April 12, 2016

Dear Mr. Jose Paul M:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143477

Device Name
Nitrile Patient Examination gloves, Powderfree, Blue color

Indications for Use *(Describe)*

The Nitrile Patient Examination gloves, Powderfree, Blue color, is a disposable device intended for medical purposes that is worn on the examiners' hand or finger to prevent contamination between patient and examiner

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (K) SUMMARY

ATTACHMENT V

K143477

1.0 SUBMITTER

1.1	Company Name	PRIMUS GLOVES PRIVATE LIMITED
1.2	Address	Plot No: 14-A, Cochin Special Economic Zone, Kakkanad, Cochin, Kerala, India - 682037
1.3	Telephone	+ 91 484 2413063
1.4	Fax	+91 484 2413089
1.5	Email	josegaul@grimusgloves.com
1.6	Contact Person	Mr. JOSE PAUL M MANAGER- QA & RA

2.0 OFFICIAL CORRESPONDENT

2.1	Company Name	PRIMUS GLOVES PRIVATE LIMITED
2.2	Address	Plot No: 14-A, Cochin Special Economic Zone, Kakkanad, Cochin, Kerala, India - 682037
2.3	Telephone	+ 91 484 2413063
2.4	Fax	+91 484 2413089
2.5	Email	josegaul@grimusgloves.com
2.6	Contact Person	Mr. JOSE PAUL M MANAGER- QA & RA

3.0 Preparation date **14th April, 2016**

4.0 Name of the device

4.1	Device Name	**NITRILE PATIENT EXAMINATION GLOVES, POWDERFREE, BLUE COLOR**
4.2	Trade Name	PRIMUS NITRILE EXAMINATION GLOVES
4.3	Common Name	PATIENT EXAMINATION GLOVES
4.4	Classification	21 CFR 880.6250 PATIENT EXAMINATION GLOVES
4.5	Class	CLASS I

4.6	Product code	LZA

5.0 Identification of the legally marketed predicate device

5.1	Device Name	ETS Blue Powderfree Nitrile patient exam glove
5.2	510(k) Number	K121947
5.3	Company	Northstar Healthcare Holdings, 70 Sir John Rogerson's Quay, Dublin 2, Ireland.
5.4	Device Description	Non sterile Nitrile powderfree exam gloves
5.5	Classification	PATIENT EXAMINATION GLOVES
5.6	Class	CLASS I
5.7	Product code	LZA
5.8	Classification Panel :	General Hospital

6.0 Description of the Device

The subject device is a patient examination glove made of synthetic nitrile latex compound. It is non-sterile, powderfree and is Blue in color. The device is ambidextrous and can be worn on either the left or right hand.
The device meets ASTM 06319-10: Standard specification for Nitrile Examination Gloves for Medical Application.
The subject device is substantially equivalent to legally marketed Nitrile examination gloves identified as Product code LZA.
The device is for over-the counter single use.

7.0 Indications for use

The Nitrile Patient Examination gloves, Powderfree, Blue color, is a disposable device intended for medical purposes that is worn on the examiners' hand or finger to prevent contamination between patient and examiner.

510 (K) SUMMARY

8.0 Summary of performance data

There is no difference in technological characteristics compared to the predicate device. Gloves are made from Nitrile latex compound, Non sterile, Powderfree and Blue in color. The gloves have the same technological characteristics compared to ASTM or equivalent standards as given below,

Characteristics	**Standards**	**Performance of Nitrile patient examination gloves, Powderfree, Blue color**
Freedom from Holes	ASTM 06319-10 / ASTM 05151-06	Meets
Dimensions	ASTM D6319-10	Meets
Physical Properties	ASTM D6319-10 / ASTM 0412-06	Meets
Powder-free residue	ASTM 06319-10	Meets
Bio-compatibility	Primary skin irritation ISO 10993-10	Non-irritant
	Skin/Dermal Sensitization ISO 10993-10	Non-sensitizer
Expiration dating/Shelf life	ASTM D7160-05	Three years

510 (K) SUMMARY

Performance data of gloves based on ASTM 06319-10 and FDA 1000ml water leak test

ASTM 06319-10 and FDA 1000 ml water leak test					
Characteristics	**Test**	**Test standard**	**Sampling plan/Inspection level/AQL**	**Non sterile, powderfree, Non sterile Nitrile examination gloves-PRIMUS**	**RESULT**
Freedom from Pin holes	FDA 1000 ml water leak test	ASTM D5151-06 (reap 2011)	ISO 2859-1 / G11AQL 2.5	PASS	PASS
Dimensions	Length	ASTM D6319-10	ISO 2859-1 / S21AQL 4.0	> 230 mm (240-400mm)	PASS
	Width	ASTM D6319-10	ISO 2859-1 / S21AQL 4.0	70±10 mm to 120±10 mm (sizes XS to XL)	PASS
	Thickness	ASTM D6319-10	ISO 2859-1 / S21AQL 4.0	> 0.05 mm (palm & finger)	PASS
Physical properties	Before aging	ASTM D6319-10 and ASTM D412-06	ISO 2859-1 / S21AQL 4.0	Tensile strength : > 14 Mpa	PASS
				Ultimate Elongation : > 500%	PASS
				Tensile	PASS

	After Accelerated aging	ASTM 06319-10 and ASTM 0412-06	ISO 2859-1 / S2/AQL 4.0	strength : > 14 Mpa	
				Ultimate Elongation : > 400 %	PASS
Powder-free residue	Powder-free residue	ASTM D6319-10 and ASTM 06124-06	N=5	Less than 2 mg per glove	PASS
Biocompatibility	Primary skin irritation	ISO 10993-10	Under the conditions of the study the device is not an irritant		PASS
	Skin/Dermal Sensitization	ISO 10993-10	Under the conditions of the study the device is not a sensitizer		PASS

9.0 Summary of the technological characteristics of device compared to the legally marketed predicate device

Characteristics	**PREDICATE-510(K) : K121947**	**SUBJECT DEVICE : K143477**	**Acceptance criteria/Standard**
Manufacturer	Northstar Healthcare Holdings, 70 Sir John Rogerson's Quay, Dublin 2, Ireland.	PRIMUS GLOVES PRIVATE LIMITED, Plot No: 14-A, CSEZ, Kakkanad, Cochin, Kerala, India -682037	
Product Name	ETS Blue Powder Free	Nitrile Patient Examination Gloves,	Patient examination

	Nitrile Patient Exam Gloves	Powderfree Blue color	gloves
Intended Use	Intended for medical purpose that is worn on the Examiners hand to prevent contamination between patient and examiner	Intended for medical purpose that is worn on the Examiners hand to prevent contamination between patient and examiner	Medical Glove Guidance Manual
Indication for use	The examination gloves is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner	The examination gloves is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner	Medical Glove Guidance Manual
Description	Non sterile powderfree , examination gloves made of nitrile and colored blue The textured gloves	Non sterile powderfree , examination gloves made of nitrile and colored blue The textured gloves are provided in sizes Extra Small, Small, Medium,	Medical Glove Guidance Manual

	are provided in sizes Extra Small, Small, Medium, Extra Large. The smooth gloves are provided in Sizes Small, Medium, Large and Extra Large	Extra Large. The smooth gloves are provided in Sizes Small, Medium, Large and Extra Large	
Presentation	Non sterile gloves are provided in dispenser boxes	Non sterile gloves are provided in dispenser boxes	Medical Glove Guidance Manual
Material	Nitrile synthetic latex	Nitrile synthetic latex	ASTM 06319-10 LZA product code
Non-sterile or sterile	Non Sterile	Non Sterile	Sterility
Single Use	Yes	Yes	Disposable/Single use
Ambidextrous	Yes	Yes	ASTM D 6319-0
Dimensions	Meets ASTM D 6319-10	Overall length min 240 mm ,width varies from 70 mm for XS size to 120 mm for XL size, thickness in finger and palm has a minimum 0.05 mm	Meets ASTM D 6319-10 -Overall length min 240 mm, width varies from 70 mm for XS size to 120 mm for XL size, thickness in finger

			and palm has a minimum 0.05 mm
Tensile Strength	Meets ASTM D 6319-10	Tensile strength 14 Mpa min for before aging and 14 Mpa min for after aging Aging done at 70 ±2 deg C for 166±2 hrs or 100±2deg C for 22±0.3 hrs	Meets ASTM D 6319-10- Tensile strength 14 Mpa min for before aging and 14 Mpa min for after aging Ultimate elongation 500 % min for before aging and 400 % min for after aging. Aging done at 70 ±2 deg C for 166±2 hrs or 100±2deg C for 22±0.3 hrs
Ultimate Elongation	Meets ASTM D 6319-10	Ultimate elongation 500 % min for before aging and 400 % min for after aging. Aging done at 70 ±2 deg C for 166±2 hrs or 100±2deg C for 22±0.3 hrs	Meets ASTM D 6319-10- Ultimate elongation 500 % min for before aging and 400% min for after aging. Aging done at 70 ±2

			deg C for 166±2 hrs or 100±2deg C for 22±0.3 hrs
Freedom from pinholes	Meets ASTM D 5151 -06 and ASTM 06319-10	Meets ASTM D 5151 -06 (2011) and ASTM 06319-10	ASTM D 5151 -06 (2011) and ASTM 06319-10
Residual Powder	Meets ASTM D 6124-06	Less than 2 mg per glove	ASTM 0 6124-06(2011) : Less than 2 mg per glove
Biocompatibility Tests ISO 10993-10	Non-irritant - Primary Skin Irritation In Rabbits	Under the conditions of the study the device is not an irritant	Under the conditions of the study the device is not an irritant
	Non-sensitizer - skin Sensitization in Guinea pigs	Under the conditions of the study the device is not a sensitizer	Under the conditions of the study the device is not a sensitizer
Labeling	Powderfree, Nitrile patient exam glove Non sterile Single use only Ambidextrous Blue color Manufactured for Lot No Intended use Quantity Country of origin	*Powderfree, *Nitrile Patient exam glove *Non sterile *Single use only *Blue color *Ambidextrous *Manufactured for *Lot No *Intended use *Quantity *Country of origin	Chapter 4- Labeling- Medical Glove Guidance Manual

10.0 CONCLUSION

The physical performance of the subject device is substantially equivalent to predicate K121947 and will perform according to the glove performance and biocompatibility standards referenced. Based on the intended use, physical properties and technological characteristics, the subject device is as safe, effective and performs as well as the legally marketed predicate device.